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09/932,122	08/16/2001	Tony Baker	077940.0103	4239

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/932,122	BAKER, TONY	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-96* is/are pending in the application.

4a) Of the above claim(s) *71-73 and 86-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-70,74-85 and 89-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1007;0208;0308a;0308b;0408*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the Amendment including a complying complete set of claims filed January 16, 2008. Claims 64, 67, 70-72, 79, 82, and 85-87 have been amended. Claims 71-73 and 86-88 are withdrawn, and claims 64-70, 74-85, and 89-96 are under consideration (see also paragraph 3, below).

Election/Restrictions

2. Applicant's election of the species of a leukocyte esterase in the reply filed on October 22, 2007 (which election was reiterated in the reply of January 16, 2008) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 71-73 and 86-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 22, 2007.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed February 11, 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Particularly, references MMM and NNN are not fully legible (because the bottom of each page of the references is cut off), and therefore have not been considered. It is also

noted that only the English language abstracts of references P, Q, S, T and MM have been considered as complete translations of the references were not provided.

5. Regarding the IDS filed April 2, 2008, it is noted that the citation of the International Search Report and Written Opinion for PCT/US07/063982 has been lined through because a publication date is not available for the reference; however, the Search Report and Written Opinion have been reviewed by the examiner.

Specification

6. It is noted that the first line of the specification should be amended so as to provide the current status of applications 09/805,785, 09/185,402, and 08/988,029.

Claim Rejections - 35 USC § 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 65, 68-69, 80, and 83-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 recites the limitation "the divalent metal chelator". There is insufficient antecedent basis for this limitation in the claim, because claim 64 refers only to a “chelator”.

Claims 68-69 recite the limitation "the divalent metal chelator". There is insufficient antecedent basis for this limitation in the claims, because claim 67 refers only to a “chelator”.

Claim 80 recites the limitation "the divalent metal chelator". There is insufficient antecedent basis for this limitation in the claim, because claim 79 refers only to a "chelator".

Claims 83-84 recite the limitation "the divalent metal chelator". There is insufficient antecedent basis for this limitation in the claims, because claim 82 refers only to a "chelator".

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 64-70, 74-85, and 89-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods employing divalent metal chelators in combination with a chelator enhancing component selected from lithium chloride, sodium perchlorate, sodium thiocyanate, and combinations thereof, does not reasonably provide enablement for methods employing any kind of chelator, and for methods in which the "chelator enhancing component" is sodium salicylate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These

factors include, but are not limited to: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (*MPEP* 2164.01(a)).

Claims 64-70 and 74-78 are drawn to methods of "suppressing the interference of a masking agent" selected from one of those listed in the preamble of the claims, which methods comprise contacting a nucleic acid containing test sample with a chelator and a “chelator enhancing component”. Claims 67-70, 74-78, 82-85, and 89-96 are drawn to methods of “improving the signal response of a molecular assay” in which nucleic acid containing samples are similarly contacted with a chelator and a chelator enhancing component prior to conducting a molecular assay on extracted molecular analytes, wherein "the signal response of the molecular assay is improved relative to a molecular assay performed” without the added chelator and chelator enhancing component. Claims 64-66 and 79-81 are limited to a chelator enhancing component selected from lithium chloride, sodium salicylate and combinations thereof, while claims 67-70, 74-78, 82-85, and 89-96 encompass these chelator enhancing components as well as sodium perchlorate and sodium thiocyanate (and combinations thereof). With regard to dependent claims 65, 68-69, 80, and 83-84, it is again noted that antecedent basis is lacking in the claims for the recitation “the divalent metal chelator”; thus, these claims are not clearly limited to the particular types of chelators recited therein.

It is unpredictable as to whether one of skill in the art could use applicant's invention in a manner commensurate with the instant claims. As noted above, the claims broadly encompass the use of any type of chelator, and recite the "chelator enhancing component" sodium salicylate. However, neither applicant's specification, nor the specifications of any of the applications from which the instant application claims priority, exemplify the use of a chelator that is not a divalent metal chelator, or the use of the chelator enhancing component sodium salicylate, in either suppressing interference of any masking agent and/or improving signal response, as set forth in the instant claims. Rather, applicant's examples are limited to the use of combinations of divalent metal chelators (particularly, e.g., EDTA, EGTA, and BAPTA) and chelator enhancers lithium chloride, guanidine, sodium perchlorate, and sodium thiocyanate in improving assay results and suppressing interference of various masking agents (see, e.g., Examples 1-2, as well as Figures 6-9 and the descriptions thereof at pages 5-6). Lacking guidance from the specification, one of skill in the art may look to the teachings of the prior art for further guidance with regard to enablement of a claimed invention. In the instant case, the prior art as exemplified by Chung et al (Mol. Cells 6(1):108-111 [1996]) and Yang et al (US 5,514,551 [07 May 1996]) discloses the use of combinations of the divalent metal chelator EDTA and lithium chloride in various molecule assays (see rejections below). However, the prior art is silent with regard to suppressing interference and/or of improving signal response (as set forth in the instant claims) using chelators other than divalent metal chelators in combination with the chelator enhancers of the claims, as well as with regard to the use of sodium salicylate as a

"chelator enhancing component" in such methods. Thus, the prior art does not provide enabling guidance with regard to those aspects of the claimed invention that are unpredictable based on the lack of guidance provided in applicant's specification. Given the high skill level of one of ordinary skill in the relevant art, it is clearly within the ability of such an artisan to conduct further experimentation aimed at determining whether sodium salicylate functions in a manner similar to, e.g., lithium chloride when employed in the combinations of the instant claims, and whether chelators other than divalent metal chelators may be successfully employed as well. However, the outcome of such experimentation is completely unpredictable, and it is unknown whether any quantity of experimentation would actually result in an artisan actually identifying additional combinations of reagents that may be used to suppress interference and/or to improve signal response. Thus, while the specification is enabling with respect to methods employing divalent metal chelators and the chelator enhancers of the claims other than sodium salicylate, it would require undue experimentation to use applicant's invention commensurate with the instant claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 64-70, 75, and 77-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al (US 5,514,551 [07 May 1996]).

It is noted that this rejection applies to claims 64-66 to the extent that the claims are drawn to methods encompassed by the claims in which about 0.1M to 1.0M of a chelator enhancing component is contacted with the test sample in combination with other reagents, and in which a "reagent consisting of from about 0.01 M to about 0.1 M of a chelator" is also provided in combination with other reagents (as set forth at, e.g., page 3 of the specification). Such methods are broadly encompassed by the claims as presently written.

With regard to claims 64 and 67 and claims dependent therefrom, Yang et al disclose a molecular assay for the detection of *C. trachomatis* rRNA comprising amplification followed by probe hybridization (see Example 1). The assay comprises a step of contacting a nucleic-acid containing test sample with a solution comprising 0.6M lithium chloride (LiCl) and 10 mM (i.e., 0.01M) of the chelator ethylenediaminetetracetic acid (EDTA) (see col 21, lines 3-8). Yang et al therefore disclose a contacting step meeting the requirements of the instant claims. With regard to the intended use of suppressing the interference of a leukocyte esterase, it is noted that this recitation does not result in any manipulative difference between the claimed method and that of Yang et al, and thus is not accorded patentable weight (see MPEP 2111.02). Further, with regard to the recitation "wherein the interference of the masking agent on the molecular assay of the nucleic acid-containing test sample is suppressed," this recitation similarly does not result in any manipulative difference between the claimed invention and that of Yang et al, but rather recites a result that inherently occurs as a result of the required "contacting" step. (It is also noted that while the claims as written do not require any

actual manipulations involving the use of the elected masking agent leukocyte esterase, the teachings of the specification establish that it is an inherent feature of *C. trachomatis* containing samples that they include the leukocyte esterase (see Example 2)). Regarding dependent claims 65 and 68-69, it is again noted that Yang et al disclose the use of the chelator EDTA. With respect to claim 66, it is an inherent property of, e.g., the amplification and hybridization solutions taught by Yang et al that they are buffers. Regarding claim 70, it is again noted that the claims do not require any actual manipulations involving any leukocyte esterase, and further that the "contacting" with a reagent meeting the requirements of the claims would inherently achieve the suppression required thereby. Regarding claim 75, it is again noted that Yang et al disclose an RNA detection assay. Regarding claims 77-78, Yang et al further disclose embodiments of their invention in which amplification by PCR precedes the hybridization with an acridinium-ester labeled probe (see, e.g., Example 13).

13. Claims 64-70, 74-76, 79-85, 89, and 93-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Chung et al (Mol. Cells 6(1):108-111 [1996]).

It is noted that this rejection applies to claims 64-66 and 79-81 to the extent that the claims are drawn to methods encompassed by the claims in which about 0.1M to 1.0M of a chelator enhancing component is contacted with the test sample in combination with other reagents, and in which the "reagent consisting of from about 0.01 M to about 0.1 M of a chelator" is also provided in combination with other reagents (as set forth at, e.g., page 3 of the specification). Such methods are broadly encompassed by the claims as presently written.

With regard to claims 64 and 67 and claims dependent therefrom, Chung et al disclose improved methods for isolating RNA from plant tissues comprising contacting pulverized plant tissues with an extraction buffer comprising 300 mM (i.e., 0.3M) LiCl and 10 mM (i.e., 0.01M) EDTA (see entire reference, particularly page 109, noting the contents of "Extraction buffer A"). Chung et al therefore disclose a contacting step meeting the requirements of the instant claims. With regard to the intended use of suppressing the interference of a leukocyte esterase, it is noted that this recitation does not result in any manipulative difference between the claimed method and that of Chung et al, and thus is not accorded patentable weight (see MPEP 2111.02). Further, with regard to the recitation "wherein the interference of the masking agent on the molecular assay of the nucleic acid-containing test sample is suppressed," this recitation similarly does not result in any manipulative difference between the claimed invention and that of Chung et al, but rather recites a result that inherently occurs as a result of the required "contacting" step.

Regarding claims 79 and 82 and claims dependent therefrom, Chung et al disclose the "contacting" step as noted above, and further disclose that the contacting step is followed by freezing and thawing and extraction of RNA (page 109, see "Procedure" description). Chung et al further disclose that isolated RNA was analyzed by spectrophotometry and agarose gel electrophoresis, and used in cDNA library construction and Northern blotting (see page 109, left column). Thus, Chung et al teach contacting, extracting, and "conducting a molecular assay" steps meeting the requirements of the claims. With regard to the intended use of suppressing the

interference of a leukocyte esterase, it is again noted that this recitation does not result in any manipulative difference between the "contacting" step of the claims and that of Chung et al. With regard to the recited intended use of "improving the signal response" of a molecular assay and the recitation "wherein the signal response of the molecular assay is improved relative to a molecular assay performed without the reagent," Chung et al disclose that their method employing buffer A improves the quality of isolated RNA relative to other methods, and improves the results of molecular assays (see entire reference, particularly pages 110-111).

Regarding dependent claims 65, 68-69, 80, and 83-84, it is again noted that Chung et al disclose the use of the chelator EDTA. With respect to claims 66 and 81, it is an inherent property of buffer A taught by Chung et al that it is a buffer. Regarding claims 70 and 85, it is again noted that the claims do not require any actual manipulations involving any leukocyte esterase, and further that the "contacting" with a reagent meeting the requirements of the claims would inherently achieve the suppression required thereby. With respect to claims 74 and 89, buffer A of Chung et al also includes 1.5% SDS (sodium dodecyl sulfate), meeting the requirements of the instant claims (see page 109, left column). Regarding claims 75 and 93, it is again noted that Chung et al disclose RNA isolation and detection. Regarding claims 76 and 94, it is an inherent property of the plant tissues employed by Chung et al that they comprise eukaryotic DNA. It is noted that claims 76 and 94 are further limiting of the contents of the sample being contacted, not of, e.g., the type of molecule extracted therefrom.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 77-78 and 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung et al (Mol. Cells 6(1):108-111 [1996]) in view of Yang et al (US 5,514,551 [07 May 1996]).

Regarding the invention of claims 77-78, Chung et al disclose improved methods for isolating RNA from plant tissues comprising contacting pulverized plant tissues with an extraction buffer comprising 300 mM (i.e., 0.3M) LiCl and 10 mM (i.e., 0.01M) EDTA (see entire reference, particularly page 109, noting the contents of "Extraction buffer A"). Chung et al therefore disclose a contacting step meeting the requirements of instant claim 67 (from which claims 77-78 depend). With regard to the intended use of suppressing the interference of a leukocyte esterase, it is noted that this recitation does not result in any manipulative difference between the claimed method and that of the prior art, and thus is not accorded patentable weight (see MPEP 2111.02). Further, with regard to the recitation "wherein the interference of the masking agent on the molecular assay of the nucleic acid-containing test sample is suppressed," this recitation similarly does not result in any manipulative difference between the claimed invention and that of the prior art, but rather recites a result that inherently occurs as a result of the required "contacting" step.

Regarding the invention of claims 95 and 96, Chung et al disclose the "contacting" step as noted above, and further disclose that the contacting step is followed by freezing and thawing and extraction of RNA (page 109, see "Procedure" description). Chung et al further disclose that isolated RNA was analyzed by spectrophotometry and agarose gel electrophoresis, and used in cDNA library construction and Northern blotting (see page 109, left column). Thus, Chung et al teach contacting, extracting, and "conducting a molecular assay" steps meeting the requirements of the claims. With regard to the intended use of suppressing the interference of a leukocyte esterase, it is again noted that this recitation does not result in any manipulative difference between the "contacting" step of the claims and that of the prior art. With regard to the recited intended use of "improving the signal response" of a molecular assay and the recitation "wherein the signal response of the molecular assay is improved relative to a molecular assay performed without the reagent," Chung et al disclose that their method employing buffer A improves the quality of isolated RNA relative to other methods, and improves the results of molecular assays (see entire reference, particularly pages 110-111).

While Chung et al disclose several types of molecular assays that may be practiced on isolated RNA, including detection of RNA by Northern hybridization (see, e.g., page 111, left column), Chung et al do not teach an assay meeting the requirements of the instant claims. Yang et al disclose that when nucleic acids are present in insufficient quantities to permit direct detection by hybridization, such nucleic acids may be amplified by methods including PCR so as to provide sufficient target

molecules for detection (see entire reference, particularly col 2, lines 33-67). In view of the teachings of Yang et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods of Chung et al so as to have detected target RNA molecules by a combination of PCR amplification and hybridization rather than by Northern hybridization. An ordinary artisan would have been motivated to have made such a modification in any instance when a greater quantity of target sequence was required to achieve detection for the advantage of allowing the detection of a small quantity of target RNA to be achieved, as specifically suggested by the teachings of Yang et al.

Terminal Disclaimer

16. The terminal disclaimer filed on April 12, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,458,546 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 64-70, 74-85, and 89-96 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-21 and 23-26 of copending Application No. 11/686,169. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims and the '169 claims are each drawn to methods in which nucleic acid containing samples (including bodily fluids) are contacted with compositions comprising a chelator and a chelator enhancing component (note the recitations in dependent claims 23-26 of the '169 application with regard to the nature of the macromolecule and its presence in bodily fluids). The types and concentrations of the chelator(s) and chelator enhancing component(s) set forth in the '169 claims are such that those claims anticipate instant claims 64-70 and 74-78. With regard to the further methods steps set forth in instant claims 79-85 and 89-96 (e.g., of extracting analytes and conducting molecular assays), such further method steps are merely obvious uses of the analytes prepared by the methods of the '169 claims (note that the methods of instant claims 64-70 and 74-78 were not restricted from those of instant claims 79-85 and 89-96 because the claims are similarly obvious variants of one another). It is also noted that the different intended uses set forth in the instant claims do not result in a

manipulative difference with respect to the '169 claims, and are not accorded patentable weight. Finally, the instant claims recite the open transitional language "comprising" and thus are sufficiently broad so as to encompass the inclusion of additional reagents, such as the base recited in the '169 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 64-70, 74-85, and 89-96 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-52 of copending Application No. 12/048,961. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims and the '961 claims are each drawn to methods in which nucleic acid containing samples (including bodily fluids) are contacted with compositions comprising a chelator and a chelator enhancing component (note the recitations in dependent claims 38-45 of the '961 application with regard to the preservation of nucleic acids and the fact that the claims encompass cells and molecules contained in bodily fluids). The types and concentrations of the chelator(s) and chelator enhancing component(s) set forth in the '961 claims are such that those claims anticipate instant claims 64-70 and 74-78. With regard to the further methods steps set forth in instant claims 79-85 and 89-96 (e.g., of extracting analytes and conducting molecular assays), such further method steps are merely obvious uses of the material prepared and preserved by the methods of the '961 claims (note that the methods of instant claims 64-70 and 74-78 were not restricted from those of instant claims 79-85 and 89-96

because the claims are similarly obvious variants of one another). It is also noted that the different intended uses set forth in the instant claims do not result in a manipulative difference with respect to the '961 claims, and are not accorded patentable weight. Finally, the instant claims recite the open transitional language "comprising" and thus are sufficiently broad so as to encompass the inclusion of additional reagents, such as the base recited in the '961 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 64-70, 74-85, and 89-96 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 24 of copending Application No. 11/774,985 (US20080064108A1 [13 March 2008]). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims and the '985 claims are each drawn to methods in which nucleic acid containing samples (including bodily fluids) are contacted with compositions comprising a chelator and a chelator enhancing component (note the recitations in claim 1 and dependent claims 8-9 of the '985 application with regard to the fact that the '985 claims, like the instant claims, encompass contacting bodily fluids with the preservation solution of the claims). While the '985 claims refer to the preservation of a protein or a small molecule, the samples employed in the methods of the '985 claims (i.e., the "bodily fluids" of the claims) inherently also include nucleic acids, and the types and concentrations of the chelator(s) and chelator enhancing component(s) set forth in the

'985 claims are such that those claims anticipate instant claims 64-70 and 74-78. With regard to the further methods steps set forth in instant claims 79-85 and 89-96 (e.g., of extracting analytes and conducting molecular assays), such further method steps are merely obvious uses of the material prepared and preserved by the methods of the '985 claims (note that the methods of instant claims 64-70 and 74-78 were not restricted from those of instant claims 79-85 and 89-96 because the claims are similarly obvious variants of one another). It is also noted that the different intended uses set forth in the instant claims do not result in a manipulative difference with respect to the '985 claims, and are not accorded patentable weight.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

21. It is noted that while the Chung et al reference was previously cited during prosecution of the application, a copy of the reference could not be located. Accordingly, the reference has been cited again and a copy is provided herewith.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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